



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M37261

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

May 2, 2000

Harshida Parmar, President
Dhanraj
829 Alvarado Street
San Leandro, CA 94577

WARNING LETTER

Dear Mrs. Parmar:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 829 Alvarado Street, San Leandro, CA on January 26-28, February 1, 3, 4, 8, 9, 11, and 17, 2000. The inspection revealed significant insanitary conditions which cause products stored in your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

The following is a list of the insanitary conditions observed by Investigator Bradley Maunder, Entomologist Dana Ludwig, and Inspector Aaron Pang:

1. Building and Grounds/ Bird Activity
 - a. Pallets of product were stacked alongside the exterior of the building in the north-side of the parking lot. At least five (5) birds were found roosting on the pallets on January 26-28, 2000.
 - b. The flour repackaging room had a damaged window screen with a triangular opening of approximately 4" x 12". The sliding glass window was missing, allowing access to the immediate environment. The door that adjoins the southwest repacking room had two small holes, which were plugged with paper material.
 - c. The plastic screens on two of the three roll-up doors on the north side of the building had missing sections, from 2' to 4' in size. The plastic screens were not sufficiently long enough to extend to the floor. A bird was observed flying into the facility through the opening of one of the screens, and another bird was observed hopping into the facility underneath the screens.

- d. Three (3) birds were observed flying in the main warehouse and roosting on ceiling structures. A bird nest was observed at the wall-ceiling juncture at the west end of the main warehouse area.
2. Rodent Activity
- a. Twenty-two (22) rodent excreta pellets were found in various locations of the warehouse.
 - b. Eight (8) rodent excreta pellets were found on or near mungdahl, which was shrink-wrapped with cellophane on a single pallet.
 - c. A rodent-gnawed coconut was found on a pallet resting on the floor near the south wall of the warehouse.
3. Insect Activity
- a. Nine (9) beetles, one of which was live, were found in various locations of the flour repackaging room.
 - b. One (1) live caterpillar, one (1) live Indian Meal Moth, two clumps of insect webbing and two (2) larvae were found on the flour mixing machinery in the flour repackaging room.
 - c. Ten (10) beetles, one of which was live and another of which was newly dead, were found on the exterior packing cartons of mustard seed, DIL RAVA, and roasted fennel seed in the packing room. The fennel seed was transferred to a new clean container.
4. Personnel
- An employee involved in the repacking of various food products was not wearing protective hair restraints
5. Bathrooms
- The employee toilet facilities in the main warehouse had no hand towels and no signs on display directing employees to wash their hands after using the bathrooms and before returning to work.

The following is a list of adulterated or misbranded products found during the inspection, most of which were corrected by voluntary destruction or relabeling:

- a. Two bags of rice were found to have excessive water damage, and one bag of rice was damaged with a hole exposing its contents. The three bags of rice were voluntarily destroyed.
- b. Leaking bags of brown sugar were voluntarily destroyed.
- c. Live insects were found in black cardamon product in both the warehouse and packing room. The cardamon products in both rooms were voluntarily destroyed. Subsequent FDA laboratory analyses of the cardamon product collected during the inspection confirmed the presence of live and dead larvae.
- d. FDA laboratory analysis of Tamarind Paste collected during the inspection reveals that the product is adulterated by insects. No holes or tears were noted in the plastic packages, so the product may likely have been adulterated prior to

importation. Note that all tamarind products are subject to country-wide detention without physical examination per Import Alert 21-07 except those products listed on the attachment. See attached copy of Import Alert 21-07.

- e. Cans of Tazgi Meetha Masala containing catechu were voluntarily destroyed. Catechu is a drug ingredient that has been deemed not generally safe and effective for its intended use.
- f. Imported Char Minar camphor tablets were relabeled with stickers indicating the tablets were to be used for religious purposes only, not for ingestion.

A food is adulterated within the meaning of Section 402(a)(3) of the Act if it consists in whole or in part of any filthy substance or is otherwise unfit for food. A food is adulterated within the meaning of Section 402(a)(4) of the Act if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated.

Our inspection has revealed that your facility has problems with rodent activity, insect activity, and bird activity. At the conclusion of the inspection, the insanitary conditions were listed on Form FDA 483 (Inspectional Observations) and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. It is your responsibility to have an effective, ongoing sanitation program which eliminates the insanitary conditions which we have observed to exist in your facility. You must have a procedure in place to deal with damaged goods, including water-damaged products and leaking products. It is also your responsibility to maintain your building and grounds to preclude the entrance of pests, especially during normal business hours.

Please advise FDA in writing within fifteen (15) working days of receipt of this letter about the measures you have taken to (1) preclude the adulteration of foods in your facility; (2) the procedures you will use to deal with damaged goods in your facility; and (3) what you intend to do with the Tamarind Paste that was found adulterated by FDA analysis.

Your response should be directed to:

Ms. Harumi Kishida, Compliance Officer
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502-7070

Sincerely,



Charles D. Moss
Acting District Director